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EXAMINER

MEHTA, ASHWIN D

ART UNIT PAPER NUMBER

1638

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/972,805

Applicant(s)

CHANDLER ET AL.

Examiner

Ashwin Mehta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-34, 81-99, 121-139, 201-219 and 341-359 is/are pending in the application.
- 4a) Of the above claim(s) 201-219 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-34, 81-99, 121-129 and 341-349 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9092004</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The objection to claims 140, 220, and 360 is withdrawn in light of their cancellation.
3. The rejection of claims 29-34, 81, 83, 85, 86, 94, 100, 125, 126, 134, 201, 205, 206, 214, 345, 346, 354 under 35 U.S.C. 112, second paragraph, are withdrawn in light of the claim amendments or cancellations.
4. The rejection of claims 29 and 34 under 35 U.S.C. 102(a) is withdrawn in light of the claim amendments.

Election/Restrictions

5. Claims 34 and 201-219 encompass non-elected subject matter: corn plants or seeds directed to varieties mop1-1 and mop3-1. Non-elected Group III encompasses these varieties. Accordingly, claim 34 will only be examined to the extent that they encompass corn plants Mop2-1, rmr1-1, and rmr2-1. Claims 201-219 are withdrawn from consideration, as they are only drawn to variety Mop1-1. The non-elected subject matter must be removed from the claims.

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Specification

6. The specification was objected to under 37 CFR 1.74 because, while Figures 6 and 24 contain multiple views identified with letters, their respective brief descriptions do not mention the letters. In response, Applicants have amended the brief descriptions of those figures (paper submitted September 9, 2004). The brief description of Figure 24 was amended by reciting "Families one through nine", which is also recited in the figure to distinguish the different parts. However, that figure also contains labels, which should be addressed in the brief description. Applicants have also indicated in their response that substitute figures were submitted (response, page 19, last paragraph). However, no substitute figures have been received.

7. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, for example on page 16, paragraph 0089 and page 81, paragraph 00295. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Objections

8. Claim 87, 90, 127, 130, 207, 210, 347, and 350 remain and claim 30 is objected to under 37 CFR 1.75(c) for failing to limit the subject matter of a previous claim, for the reasons of record stated in the Office action mailed June 9, 2004. Applicants traverse the objection in the paper filed September 9, 2004. Applicants' arguments were fully considered but were not found persuasive.

Applicants argue that MPEP 601(n) III states that a claim may be properly dependent

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where the dependent claim may not be practiced without the independent claim, and provides the example that a claim that covers the product of a method, where the method claimed in an independent claim may properly depend from the independent claim, since the method must be practiced to generate the product. Applicants argue that here, the seed is produced from the plant of the independent claim (response, page 20, 1st full paragraph).

However, the instant claims do not recite any methods. Both claim 87, for example, and its parent claim 82 are directed to products. The seed of claim 87 is not a part of the plant of claim 82, but rather represents the next generation. MPEP 601(n) III states that the test as to whether a claim is a proper dependent claim is that it shall include every limitation of the claim from which it depends, or in other words that it shall not conceivably be infringed by anything which would not also infringe the basic claim. Here, the seed of claim 87 can be infringed without also infringing the plant of claim 82, since a plant produced by growing the seed of claim 87 does not possess all of the traits possessed by the plant of claim 82. There is no mention of a method in which the plant of claim 82 was used to make the seed of claim 87.

Claim Rejections - 35 USC § 112

9. Claims 91, 131, and 351 remain, and claims 29-34, 83, 85, 87-90, 91-93, 95-99, 125, 127-134, 138-139, 212-213, 345, 347-354, 358, and 359 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record stated in the Office action mailed June 9, 2004, or stated below. Applicants traverse the rejection in the paper

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filed September 9, 2004. Applicants' arguments were fully considered but were not found persuasive.

Claims 91, 94, 131, 134, 211, 214, 351, and 354 were found indefinite because of the recitation, "capable of expressing". Applicants argue that the recitation was replaced with "having" or "has" (response, page 21, 4th full paragraph). This amendment was sufficient to overcome the rejection for claims 94, 134, 214 (withdrawn), and 354. However, the term "can" in the recitation, "wherein the tissue culture can regenerate into a plant having" renders the claims 91, 131, and 351 indefinite (claim 211 is withdrawn). It is unclear whether other types of corn plants that "can" be regenerated from the tissue culture are encompassed by the claims. It is suggested that the recitation, "can regenerate" be replaced with --regenerates--.

In claims 29-31, 87, 90, 95, 98, 99, 127-130, 347, 349, and 350: the recitation, "the transgene is hypomethylated" renders the claim indefinite. The claim does not clearly indicate whether the transgene is hypomethylated in the non-mutant transgenic corn plant. If it is not, it is unclear how one would determine that it is hypomethylated, as opposed to other methylation states.

In claims 30 and 31: the recitation, "Mutant, transgenic seed" or "Progeny mutant, transgenic seed" render the claims indefinite. The claims do not make exactly clear whether the mutation is the same as that of claim 29, or some other mutation.

In claims 83, 87-90: the recitation, "Mutant, transgenic seed" or "Progeny mutant seed" or "mutant, transgenic corn seed" renders the claims indefinite. It is unclear if the mutation is the same as that in the corn seed of claim 81 or 82, or if it can be some other mutation. That is, have they inherited the mutant *rmr2-1* allele?

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In claims 85, 125, and 345: the recitation, "genotypic characteristics" renders the claim indefinite. It is not exactly clear what is referred to by the recitation. For example, is the recitation referring to the genotype, or some other characteristics, etc? If it is the genotype that is being referred to, it is suggested that the recitation be replaced with --genotype--.

In claims 91, 130, and 351: the term, "mutant," in the recitation, "a tissue culture of regenerable mutant cells of corn plant genotypically designated *rmr2-1*" in claim 91 renders the claim indefinite. Plant *rmr2-1* is a mutant plant. The term "mutant" in the recitation makes it confusing as to whether mutation of the cells of the tissue culture is the same mutation, or some other mutation(s). It is suggested that the term, "mutant" be removed from line 1. Claims 130 are indefinite for the same reason.

In claims 98 and 99: similar to claims 83, 87-90 above, it is unclear whether the mutation of the claims seed or plant is the same as *rmr2-1*.

In claims 127-130, 347-350: the recitations, "Mutant, transgenic seed" or "Progeny mutant, transgenic seed" or "mutant, transgenic corn plant" or "mutant, transgenic corn seed" renders the claims indefinite, for the same reasons as claims 83, 87-90 above.

In claims 131 and 351: the recitation, "mutant, transgenic cells of a corn plant genotypically designated *Mop2-1* (or *rmr1-1*)" renders the claim indefinite. Corn plants *Mop2-1* and *rmr1-1* are not transgenic.

In claims 138-139: it is unclear whether the mutation in the claimed hybrid seed and plant is the same as *Mop2-1*.

In claim 345: the claim is directed to a transgenic corn plant having the genotypic characteristics of the plant of claim 342. However, the plant of claim 342 is not transgenic.

In claim 348: the claim is directed to a mutant, transgenic corn plant produced from the seed of claim 348. However, the claim is indefinite because the seed of claim 348 is not transgenic.

In claim 350: the recitation, “a transgene” in line 2 renders the claim indefinite. The article “a” in the recitation makes it unclear whether the transgene of this recitation is the same as that mentioned in claim 349.

In claims 358-359: it is unclear whether the mutation in the claimed hybrid seed and plant is the same as *rmr1-1*.

10. Claims 29-34, 81-99, 121-139, and 341-359 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed June 9, 2004. Applicants traverse the rejection in the paper filed September 9, 2004. Applicants’ arguments were fully considered but were not found persuasive.

Regarding claims 29-34, Applicants argue that the claims recite an allegedly clear structural limitation, a hypomethylated transgene. Applicants argue that the recitation, “mutant” remaining in the preamble is not intended as an express limitation intended to cover specific mutations, and to differentiate between naturally existing plants and the claimed plants generated by human intervention (response, page 22, 3rd full paragraph). However, the specification does not indicate that any such plant, wherein the mutant can be by any type of mutation, is part of the

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invention. Rather, the mutation is very relevant to the claimed invention. The specification concerns paramutation. In the context explained by Applicants in the response, the invention of claims 29-33 constitute NEW MATTER that must be deleted, if the mutation is supposedly irrelevant.

Further, the specification only discusses four mutant plants, Mop1-1, Mop2-1, rmr1-1, and rmr2-1, which, when transformed to comprise a transgene, have the phenotype recited in the claims (Mop1-1 is part of a non-elected group). These plants are not representative of other mutant transgenic corn plants of the genus, as the structure of the mutations can differ in any manner from Mop1-1, Mop2-1, rmr1-1, and rmr2-1. The identity of the transgene is irrelevant, and it is the action of the mutation that affects its level of methylation and expression. The specification does not describe any other type of mutation that affects the level of methylation and expression of a transgene. No other structures are described in the specification that is correlated with this function.

Regarding claims 81-99, 121-139, and 341-359, and the issue of deposit of seeds with the ATCC, Applicants argue that the conditions of 37 CFR 1.801-1.809, and request the identification of any other section of the CFR or MPEP that indicates that the deposit requirements have not been met (response, page 23, 1st full paragraph). Applicants have not met several of the conditions for deposit of a biological material. The address of the depository must be provided (37 CFR 1.809(d)(4)). However, the address for the ATCC stated in the specification, including the amendments submitted February 28, 2002, is incorrect. Line 3 of paragraph 00173 of the specification indicates alternatively that the deposit will be maintained for the "effective" life of the patent. However, this statement must read, --enforceable-- life of

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the patent (37 CFR 1.806). Assurance has not been provided of the viability of the seeds at the time of deposit (37 CFR 1.807). There is no indication that during the pendency of the application, access to the invention will be afforded to the Commissioner upon request (37 CFR 1.808(a)(1)).

Regarding the issue concerning claims encompassed hybrid seeds and plants, Applicants argue that the claims have been amended to specify that the hybrids have the claimed structural and related functional limitations of the parent, specifically the hypomethylated transgene where the expression of said transgene is at least a two-fold higher as compared to the expression of the transgene in a non-mutant transgenic corn plant (response, paragraph bridging pages 23-24). However, regarding claims 30 and 31, the claimed hybrids are not described for the reasons discussed above. Regarding the hybrids that are descendants the claimed varieties deposited with the ATCC, the claims do not indicate that the mutations in the hybrid are the same as that of the parent plant deposited with the ATCC. No other structures are described that are correlated with the activity of causing hypomethylation and increased expression of a transgene.

11. Claims 34, 81-99, 121-139, and 341-359 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record stated in the Office action mailed June 9, 2004. Applicants traverse the rejection in the paper filed September 9, 2004. Applicants' arguments were fully considered but were not found persuasive.

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Applicants again argue that the deposit requirements of 37 CFR 1.801-1.809 have been met (response, page 24, 2nd full paragraph). However, all of the conditions have not been met, as discussed above.

12. Claims 29-34, 87, 90, 95-99, 127-134, 345, 347, and 349-354 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for mutant transgenic corn plants or seeds wherein the transgene is B-I and the host corn plant is Mop2-1, rmr1-1, or rmr2-1, does not reasonably provide enablement for any other mutant, transgenic corn plants, seeds or tissue cultures, or for the increase in expression of all types of transgenes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn towards any mutant, transgenic corn plant comprising a transgene, wherein the transgene is hypomethylated and the expression of said transgene is at least a two-fold higher to expression non-mutant transgenic corn plant; progeny seed of said mutant transgenic plant; a tissue culture of regenerable cells of said mutant plant; mutant transgenic corn seed, wherein the host seed is genotypically designated rmr2-1 said seed comprising a transgene, wherein the transgene is hypomethylated and the expression of said transgene is at least a two-fold higher to expression non-mutant transgenic corn plant; a process of producing mutant, transgenic corn seed, comprising self-pollinating a transgenic plant designated rmr2-1, or crossing to another corn plant, and hybrid corn seeds and plants produced from said process; corn seed designated Mop2-1 comprising a hypomethylated transgene that is

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expressed at a 2-fold higher level compared to expression in a non-mutant corn seed; a corn plant produced from said seed; progeny seed produced from said plant; a plant produced from said progeny seed, and a seed produced from that plant; a tissue culture of regenerable cells from plant Mop2-1; a corn plant regenerated from said tissue culture; a process of producing corn seed comprising self-pollinating plant Mop2-1, or crossing one of said plants with a second plant, and hybrid corn seed and plant produced from said cross; a mutant transgenic corn plant having the genotypic characteristics of corn plant *rmr1-1*, or mutant transgenic seed produced from said plant; or a tissue culture of regenerable mutant, transgenic cells of corn plant *rmr1-1*, a corn plant regenerated from said culture.

The specification indicates that paramutation involves an interaction between two alleles that leads to a heritable reduction in expression of one of the alleles. Alleles sensitive to reduced expression are “paramutable,” and alleles inducing the change, “paramutagenic.” Following paramutation, sensitive alleles are termed “paramutant” (page 20, paragraph 00116). The specification indicates that mutants defective in paramutation were tested for their effect on transgene silencing. Transgenic plants were produced that comprised various “B” transgenes, which encodes a transcription factor that activates the anthocyanin biosynthetic pathway. Expression of B gives rise to purple pigmentation. One transgenic corn line carries a construct comprising a 35S promoter driving expression of B-I. Expression of this transgene was not phenotypically detectable in the plant, but was detectable in aleurone layer of seeds. Another transgenic corn line carries a construct comprising the “B-Boliva” promoter fused to B-I. The original transgenic line expressed the construct in the plant and aleurone layer of the seed, but plant pigmentation was lost in subsequent generations (page 90, paragraph 00323). The

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specification discusses experiments in which four mutant plants defective in paramutation, Mop1-1 (non-elected), Mop2-1, rmr1-1, and rmr2-1, were crossed with the transgenic B-I lines, and resulted in progeny plants in which silencing of B was lifted. The activation of the B transgene occurred at the transcriptional level in the presence of the Mop1-1 and rmr2-1 mutations. These mutations can heritably activate the transgene, such that the transgene remains active when the mutation is segregated away (pages 90-95, Example 5).

However, the specification does not teach that any and all types of transgenes will be hypomethylated and be expressed at a two-fold or higher level in the claimed plants, seeds, and tissue cultures. All of the examples in the specification involved the use of one type of transgenic coding region, B-I. It is unclear that the results with this transgene can be extended to any and all transgenes. Chandler et al. (Nature Rev. Genet., 2004, Vol. 5, pages 532-544) teach that the reactivation of several transcriptionally silenced transgenes was tested in a corn plant comprising a mutation at the mop1 locus, and that not all transgenes were reactivated. Chandler et al. suggest that multiple mechanisms might be involved in different examples of silencing (page 536). In the absence of further guidance, undue experimentation would be required by one skilled in the art to determine what types of transgenes can be hypomethylated, such as to increase their expression at least two-fold, in the numerous mutant, transgenic corn plants, seeds, and tissue cultures encompassed by the claims.

Further, claim 29 encompasses transgenic corn plants that can comprise any type of mutation. However, the specification only discusses paramutation, and only teaches several corn plants with a paramutagenic allele, seed of which have been deposited with the ATCC. Of these deposited lines, only four are taught as having relieved the silencing of the B-I transgene, as

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discussed above. The specification does not teach any other type of mutant corn plant. No guidance is provided in the specification as to how one skilled in the art would make any other type of mutant, transgenic corn plant, or what other types of mutations have such an effect on transgene methylation and expression. See Genentech, Inc. v. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that “the specification, not the knowledge of one skilled in the art” must supply the enabling aspects of the invention. Given the breadth of the claims encompassing any and all types of mutant corn plants comprising any and all types of transgenes, wherein the transgene is hypomethylated and whose expression is increased at least 2-fold, unpredictability of the art and lack of guidance of the specification as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

Claim Rejections - 35 USC § 102

13. Claims 341-346, and 354 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Chandler et al. (Plant Mol. Biol., June 2000, Vol. 43, pages 121-145).

The claims are broadly drawn towards mutant corn seed genotypically designated *rmr1-1*; a corn plant produced from said seed; a mutant corn plant having all of the genotypic, phenotypic, and morphological characteristics of a plant produced from said seed; pollen or an ovule of said plant; a population of plants produced by growing said seed; or a corn plant regenerated from a tissue culture of regenerable mutant, transgenic cells of corn plant genotypically designated *rmr1-1*, wherein the plant has all of the physiological and morphological characteristics of the corn plant designated *rmr1-1*.

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Chandler et al. teach mutant corn plant *rmr1-1* (page 138). As the plant is taught, the seed that produces that plant is also inherently taught, as well as parts of that plant. There is no indication that the plant taught by the reference was regenerated from a tissue culture of cells of plant *rmr1-1*. However, the plant taught by the reference and the plant claimed in claim 354 are identical. It is noted that claim 354 indicates that the tissue culture is of regenerable mutant, transgenic cells. However, the claim is included in this rejection as it is unclear whether the cells of the tissue culture are actually transgenic, since they are of corn plant *rmr1-1*, which is not transgenic (see the indefinite rejection above). Similarly, claim 345 is included because it is unclear whether the claimed plant is transgenic.

Claim Rejections - 35 USC § 103

14. Claims 341-346, 348, and 351-359 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chandler et al. (Plant Mol. Biol., June 2000, Vol. 43, pages 121-145).

The claims are broadly drawn towards mutant corn seed genotypically designated *rmr1-1*; a corn plant produced from said seed; a mutant corn plant having all of the genotypic, phenotypic, and morphological characteristics of a plant produced from said seed; pollen or an ovule of said plant; a population of plants produced by growing said seed; or a corn plant regenerated from a tissue culture of regenerable mutant, transgenic cells of corn plant genotypically designated *rmr1-1*, wherein the plant has all of the physiological and morphological characteristics of the corn plant designated *rmr1-1*; progeny seed produced from crossing said plant with itself or another corn plant; a tissue culture of regenerable mutant, transgenic cells of corn plant genotypically designated *rmr1-1*; a process of producing mutant

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corn seed comprising self-pollinating *rmr1-1* or crossing *rmr1-1* with a different corn plant, and hybrid mutant corn seeds and plants produced by said method.

Chandler et al. is discussed above.

Chandler et al. do not teach tissue cultures of regenerable cells, progeny seeds or plants.

It would have been obvious and within the scope of one of ordinary skill in the art at the time the invention was made to produce tissue cultures of regenerable cells of the mutant plants of Chandler et al., or to cross the mutant plant of Chandler et al., either to themselves or with other corn plants, to produce seeds and plants of the following generation. One would obviously have been motivated to do so for the purpose of propagation. The cells used to make the tissue culture could have been from any choice of tissue, including embryos, meristematic cells, immature tassels, etc., or of callus or protoplasts produced from the cells. The choice of cells would have depended on one's desired end, amounting to an optimization of process parameters. It also would have been obvious to emasculate one of the corn plants involved in the cross to make the progeny plants, so as to control pollination.

15. Claims 29-34, 81-99, 121-139, and 341-359 remain rejected, and claims 201-219 are withdrawn as being drawn to a non-elected invention.

Contact Information

Any inquiry concerning this or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Patent applicants with problems or questions regarding electronic images that can be viewed in the

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November 22, 2004



Ashwin D. Mehta, Ph.D.
Primary Examiner
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